SmartPA Criteria Proposal

Drug/Drug Class:	Antiandrogenic Agents PDL Edit
First Implementation Date:	April 2, 2020
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Antiandrogenic agents inhibit the action of androgens on tumor growth in prostatic tissue. Most drugs in this class work by interfering with androgen receptor activation, androgen receptor signaling, or androgen biosynthesis. Most are indicated for use in metastatic prostate cancer, aside from additional indications of nonmetastatic castration resistant prostate cancer in Nubeqa® (darolutamide) and Xtandi® (enzalutamide). All second generation antiandrogenic agents should be given with gonadotropin-releasing hormone analog, aside from Erleada®, which should be given concurrently with androgen deprivation therapy. Dosage adjustment are required for Xtandi in patients taking concomitant strong CYP2C8 inhibitors or concomitant strong CYP3A4 inducers. Due to the mechanism of action for this class of drugs, patients may experience similar symptoms as those with androgen deficiency, including gynecomastia, and may increase risk for heart disease.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Abiraterone • Xtandi® Caps • Zytiga® 500 mg	• Erleada® • Nubeqa® • **Xtandi® Tabs** • Yonsa® • Zytiga® 250 mg

Type of Criteria:
☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Antiandrogenic Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial of preferred agents:
  - For Yonsa: therapeutic trial of abiraterone and Xtandi **capsules**
  - For Nubeqa and Erleada: therapeutic trial of Xtandi **capsules**
  - For Zytiga 250 mg: Clinical Consultant Review required for approval
  - **For Xtandi tablets: therapeutic trial of Xtandi capsules**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: "Antiandrogens, Second Generation – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: "Non-Steroidal Antiandrogens/Androgen Biosynthesis Inhibitors", UMKC-DIC; August 2021.
- Erleada® (apalutamide) [package insert]. Horsham, PA: Janssen Products, LP; September 2021.
- Nubeqa® (darolutamide) [package insert]. Bayer HealthCare Pharmaceuticals Inc.; January 2021.
- Xtandi® (enzalutamide) [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; July 2021.
- Yonsa® (abiraterone acetate) [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; March 2021.
- Zytiga® (abiraterone acetate) [package insert]. Horsham, PA: Janssen Biotech, Inc..; August 2021.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.